

ing,  $p=0.007$ , role limitation due to physical problems,  $p=0.047$ , role limitation due to emotional problems,  $p=0.036$ , and vitality,  $p=0.000$ ), but not the type of randomized strategy. Also patients < 69 years (social functioning,  $p=0.03$ , and pain,  $p=0.044$ ), AF duration < 1 month (social functioning,  $p=0.032$ ), and those with complaints of AF at baseline (role limitation due to physical problems,  $p=0.041$ ) showed QoL improvement.

**Conclusion:** Maintenance of sinus rhythm rather than the assigned strategy is an important parameter for improvement of QoL.

9:45 a.m.

803-3

### The Detection of Left Atrial Thrombi in Patients With Atrial Fibrillation Were Associated With Thromboembolic Events During Long-Term Follow-Up

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Aim of the study was evaluate the long-term outcome in patients (pts) with atrial fibrillation (AF), in whom a left atrial thrombus was detected by transesophageal echocardiography (TEE) in comparison to pts without thrombus.

**Methods:** In this single center observational study all pts were enrolled in this analysis if they were admitted to our hospital for the first time with the attention to cardiovert atrial fibrillation in sinus rhythm.

**Results:** Overall 447 pts were included in this study and in all pts TEE was performed. In 42 pts the left atrial thrombus was detected. 34 of these 42 pts (80%) were effectively anticoagulated with an INR (2–3). TEE was repeated in 31 of these 42 pts after 4–8 weeks. No left atrial thrombus was found in 20 pts. These 20 pts were then cardioverted. In the remaining 11 pts the left atrial thrombus was still present. During follow up of a median of 20 months 4 of these 42 pts had an embolic event (9.5%). All pts with a thrombus had an effective anticoagulation (INR 2-3) after discharge of the hospital. During the same follow up period 12/405 pts without a thrombus had a thromboembolic event (2.8%). Of these 405 pts 83% were effectively anticoagulated. **Conclusion:** Embolic event rate in pts with a left atrial thrombus is 9.5% in contrast to only 2.8% in pts without a thrombus during a median follow-up time of 20 months.

10:00 a.m.

803-4

### An Endovascular Approach to Stroke Prevention in Atrial Fibrillation: Results of the Multicenter PLAATO (Percutaneous Left Atrial Appendage Transcatheter Occlusion) Feasibility Trial

Mark Reisman, William Gray, Horst Sievert, Paul Kramer, Peter C. Block, Carlo DiMario, Antonio L. Bartorelli, Paolo Della Bella, Heyder Omran, Athena Poppas, David O. Williams, Allan Skanes, Bernhard Meier, Toshiko Nakai, Michael D. Lesh, Swedish Heart Institute, Seattle, WA

**Background:** Thromboembolism due to atrial fibrillation (AF) is a frequent cause of stroke. During non-rheumatic AF, thrombus originates predominantly in the left atrial appendage (LAA). Anticoagulation (warfarin) therapy has demonstrated a two-thirds reduction in stroke risk. In pts suboptimal for warfarin therapy, occlusion of the LAA may significantly reduce the risk of thromboembolism. The purpose of this phase one study is to determine the safety and feasibility of the PLAATO™ procedure in high risk AF pts who are poor warfarin candidates.

**Methods:** Patients were enrolled who have chronic or paroxysmal AF and are at high risk for stroke based on the presence of congestive heart failure, diabetes mellitus, hypertension, history of stroke/transient ischemic attack (TIA), or high-risk echo findings with transesophageal echocardiography (TEE). Patients with existing LAA thrombus were excluded. The PLAATO system consists of a self-expanding cage covered with ePTFE delivered through a 12Fr transseptal sheath specially designed to access the LAA. Device placement is guided by fluoroscopy and TEE.

**Results:** A total of 56 pts, age  $70 \pm 7$  yrs (M/F=36/20) were enrolled. Device deployment was successful in 55/56 pts (98%). One pt had a groin complication during venous access so the procedure was aborted. Seventeen of 56 pts had a history of Stroke/TIA and 26/56 pts had high risk echo findings defined as low LAA emptying velocity or spontaneous echo contrast in the LAA. Devices were oversized by 20%-50% of LAA diameter. Procedure time was  $76 \pm 30$  min. Procedural complication occurred in 6 pts (10%) and included 3 pericardial effusion, 2 groin hematoma and 1 false aneurysm. TEE follow-up at 6 mos (33 pts) included 1 death (not device related) and 0 CVA's. TEE follow-up at 6 mos (16 pts) confirmed stable implant position with a smooth atrial-facing surface. In one pt, a smooth echodense layer was seen along device surface at 1 and 6 mos, which resolved at 9 mos: no clinical events have occurred in this pt.

**Conclusions:** Transcatheter occlusion of the LAA with a novel implantable device appears feasible and safe. Whether or not it confers protection against stroke will be predicated from our long term clinical follow-up.

10:15 a.m.

803-5

### Sinus Rhythm Control in Atrial Fibrillation: Outcomes From a Controlled Long-Term Ablation Study

Carlo Pappone, Salvatore Rosanio, Giuseppe Augello, Alessia Pappone, Patrizio Mazzone, Simone Gulletta, Mario Pittalis, Gabriele Paglino, Gabriele Vicedomini, San Raffaele University Hospital, Milan, Italy

**Background:** Atrial fibrillation (AF) is associated with a 1.5- to 1.9-fold mortality risk and 2.6- to 4.5-fold risk of stroke as compared with subjects in sinus rhythm (SR). Circumferential pulmonary vein ablation (CPVA) has emerged as safe and effective treatment for curing atrial fibrillation (AF). However only limited evidence exists to support a clinical

benefit of maintaining SR beyond preventing symptoms.

**Objective:** To test retrospectively the hypothesis that long-term maintenance of SR translates in prolonged survival and reduced morbidity.

**Methods:** 589 ablated patients (pts) (mean age,  $65 \pm 9$  yrs; chronic AF, 21%; mean AF duration, 2.9 yrs) were compared with 582 ( $65 \pm 10$  yrs; chronic AF, 19%; mean AF duration, 2.1 yrs) who were given antiarrhythmic drugs for preventing recurrent AF, between January 1998 and March 2001. For both groups follow-up, including serial visits, 24-hour Holter recordings and echocardiograms, began at hospital discharge, ended in March 2002, and averaged 854 days.

**Results:** At final analysis, 20% of ablated patients and 58% among medically treated have had their first relapses ( $P<0.001$ , by log-rank statistic). Cox proportional hazard model revealed ablation was 3-fold as efficacious as drugs in preventing recurrences (hazard ratio [HR], 0.31, 95%CI 0.22 to 0.47,  $P=0.002$ ). When entered as a time-dependent variable into the Cox model, maintenance of SR, was associated with substantial reductions in the risk of death (HR, 0.46, 95%CI 0.22 to 0.68;  $P<0.001$ ) and major morbidities mainly due to heart failure and stroke (HR, 0.45, 95%CI 0.21 to 0.57;  $P<0.001$ ), either considering all patients or the two treatment groups separately (ratio of HRs 0.99,  $P=0.78$ ).

**Conclusion:** These results question the conclusions of the AFFIRM trial about the lack of benefit of SR control over rate control by drugs in AF pts, and substantiate the claim that obtaining SR is more important than using SR as a marker of good health. That SR resulted as a strong prognostic determinant reinforces the concept that, AF, by itself or as hastening factor, may cause excess mortality and morbidity. Thereby, its prevention and suppression should always be pursued.

## ORAL CONTRIBUTIONS

### 814 Electrocardiographic Predictors of Cardiac Mortality

Monday, March 31, 2003, 11:00 a.m.-12:15 p.m.

McCormick Place, Room S404

11:00 a.m.

814-1

### Lack of QT Prolongation With Amiodarone Increases Arrhythmic Risk

Peter Smetana, Esther Pueyo, Katerina Hnatkova, Marek Malik, St. George's Hospital Medical School, London, United Kingdom

**Background:** The superior anti-arrhythmic efficacy of amiodarone (A) is partly explained by an almost heart rate independent prolongation of the QT interval. Thus A treated patients with reduced QT prolongation might be at higher arrhythmic risk. We therefore investigated QT intervals at different heart rates in A and placebo (P) treated post-myocardial infarction (MI) patients. **Methods:** In 24-hours recordings from 866 EMIAT patients (462 A, 404 P) obtained 1 month after randomisation, QT intervals were obtained automatically by using the Pathfinder software (Reynolds Med Tec). QT values were averaged over 10-ms RR interval bins from 550 to 1150 ms in each recording. Results were compared between survivors (SUR, circles) and victims of non-arrhythmic (NAD, dots) and arrhythmic death (AD, triangles) both in A (left panel) and P (right panel) groups. **Results:** As expected QT intervals were significantly longer at all investigated RR interval bins on A. However, whereas there was no significant difference in the QT intervals between SUR, NAD and AD patients in the P arm (SUR vs AD at 540-550 ms:  $338 \pm 25$  vs  $337 \pm 23$  ms,  $p=ns$  and at 1140-1150 ms:  $428 \pm 40$  vs  $417 \pm 48$  ms,  $p=ns$ ), QT intervals in the A arm were shorter in AD patients than in SUR at all RR interval bins (SUR vs AD at 540-550 ms:  $349 \pm 24$  vs  $346 \pm 20$  ms,  $p=ns$  and at 1140-1150 ms:  $469 \pm 40$  vs  $423 \pm 20$  ms,  $p=2 \times 10^{-4}$ ).

**Conclusions:** Reduced prolongation of QT interval by A increases the risk of AD in post-MI patients.

